July 2018

RBB Brief 56

RBB | Economics

Pfizer/Flynn vs the CMA: Misdiagnosis of excessive pricing

On 07 June 2018, the UK Competition Appeals Tribunal ('CAT') set aside the Competition and Markets Authority ('CMA') Decision regarding the alleged excessive pricing of phenytoin sodium (an anti-epileptic drug) by two pharmaceutical companies – Pfizer and Flynn.[1] [2]

While the CAT supported the CMA's findings in relation to market definition and dominance, it was critical of the CMA's assessment of the alleged abusive conduct. Specifically, the CAT found that the CMA "did not correctly apply the legal test for finding that prices were unfair; it did not appropriately consider what was the right economic value for the product at issue; and it did not take sufficient account of the situation of other, comparable, products, in particular of the phenytoin sodium tablet".[3]

In short, the CAT found that the CMA had failed to conduct a thorough economic assessment of the circumstances in which prices can be held to be excessive and identified a range of factors that need to be considered in order to robustly establish a finding of excessive pricing. The CAT Judgment therefore serves as a welcome reminder of the inherent difficulties that arise in determining whether or not a given price level can be meaningfully determined to be excessive and, perhaps more importantly, that competition authorities should not ignore crucial economic evidence in that assessment.

This Brief explores the economics of excessive pricing, and discusses some of the substantive factors underpinning the CAT's criticism of the CMA Decision.

The problematic economics of excessive pricing

For economists, excessive pricing is arguably the most contentious and controversial area of competition enforcement. In particular, whilst it is well-established that consumers benefit when prices are set at competitive levels, determining what constitutes the competitive price in practice is not straightforward. It is clearly the case that a firm's short run marginal cost of production cannot be used as a practical benchmark for competitive prices since whenever a firm incurs fixed costs, pricing at short run marginal cost would not be sustainable. Furthermore, a firm's total costs (including both fixed and marginal costs) would also constitute a poor benchmark as more efficient companies, or those with more desirable products, may be able to sustain prices that are significantly above this level in competitive market conditions. Indeed, this ability to earn margins in excess of their costs of supply provides the reward for firms that successfully invest in innovative new products, therefore serving to encourage dynamic competition. Hence, since it is to be expected that firms may earn substantial positive margins even under competitive conditions, we are left with the question of when a particular level of margin should be seen as excessive.

The legal test for excessive pricing does little to overcome this difficulty. In United Brands, the European Court of Justice ('ECJ') defined an unlawful price as one that "has no reasonable relation to the economic value of the product supplied".[4] In order to implement this standard the ECJ also set down a test based on two cumulative conditions: (1) "to determine whether the difference between the costs actually incurred and the price actually charged is excessive" and if so; (2) "to consider whether the price imposed is either unfair in itself or when compared to competing products".

The first "limb" of the United Brands test requires practitioners to determine whether the difference between costs and prices is "excessive". However, as prices will exceed costs by a material amount in many markets, it is hard to distinguish between differences in costs and prices that might be found under conditions of effective competition, and those which are so high as to be excessive.

1. The CAT Judgment is available at http://www.catribunal.org.uk/237-9687/1276-1-12-17--Pfizer-Inc-and-Pfizer-Limited.html. The CMA Decision, published in December 2016, is available at https://assets.publishing.service.gov.uk/media/594240cfe5274a5e4e00024e/phenytoin-full-non-confidential-decision.pdf. The CMA Decision was made under Chapter II provisions of UK Competition Act 1998 which mirror Article 102 of the TFEU. The CMA announced on 28 June 2018 that it would appeal the Judgment.

2. RBB acted for Pfizer throughout the CMA investigation and the subsequent Appeal.

3. CAT Judgment paragraph 4.

4. United Brands Company and United Brands Continentaal BV v Commission of the European Communities https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:61976CJ0027&from=EN

The second limb of the test then requires an assessment of whether a price is "unfair in itself" (in the sense that it does not truly reflect the economic value of the good or service in question) or "when compared to competing products".

The first component of this second limb would seem to ask practitioners to objectively quantify the true value of a product to the consumers that purchase it. In so doing, it rightly seeks to recognise that demand side considerations might warrant pricing substantially in excess of costs. However, implementing a sensible concept of economic value is fraught with difficulties. From an economic perspective the "value" of a product is typically defined as the maximum amount an individual is willing to sacrifice to procure that product (or, equivalently, as their willingness to pay). However, this definition does not translate easily into a sensible legal test. In particular, customers that are observed to pay the prevailing price for a product will always, by definition, value it at least at the price paid. Using this definition of value would therefore define excessive prices out of existence as the observed (and allegedly excessive) price would always be lower than the value ascribed to it by consumers of the product.

The second part of the second limb – namely whether prices are unfair when compared to other products – highlights the importance of reflecting the market context in any analysis of excessive pricing. This is a more sensible test as it seeks to compare prices to those of comparable products that arise under normal competitive conditions. However the implementation of this test is nevertheless still controversial, not least because it is hard in many cases to identify other products that are sufficiently similar to the product under investigation to act as a valid benchmark.

Background to the CMA investigation

Phenytoin sodium is an off-patent pharmaceutical product used for the treatment of epilepsy. Before 2012, Pfizer had sold its version of phenytoin sodium in capsule form under the brand name Epanutin. As Epanutin was a branded product during this period its price was regulated under the UK Pharmaceutical Price Regulation Scheme ('PPRS').[5]

In September 2012, Pfizer sold Epanutin's UK Marketing Authorisation (i.e. the approval right to market this product) to Flynn, while Pfizer continued to operate as an upstream manufacturer of the capsules under an exclusive supply agreement. Following the sale, Flynn "genericised" Epanutin – i.e. obtained approval to sell the product as a generic, rather than a branded, product – and the product was withdrawn from the PPRS. Flynn then reset the retail price of Pfizer-produced phenytoin sodium to the level of the closest comparable product available in the market: namely Teva's phenytoin sodium tablet.[6] This led to an increase of the price of phenytoin sodium charged to the NHS of around 2,600%, resulting in significant press attention and ultimately leading the CMA to open its investigation.[7]

Based on these facts the CMA brought a case against Pfizer and Flynn which at first glance appeared beguilingly simple.

First, in addressing the first limb of the United Brands test it deployed a "cost plus" test. The CMA's "cost plus" benchmark encompassed the direct and (apportioned) indirect costs of producing the product and a "reasonable return" of 6%": this "reasonable return" was based on the return on sales allowed under PPRS for companies' portfolios of branded medicines.[8] As Pfizer's actual margin materially exceeded this level it argued that those prices must be deemed excessive.

Second, in addressing limb two of the United Brands test, the CMA sought to boil down the question to a characteristics assessment of the product. In particular, it argued that since phenytoin sodium was an old drug that did not stand out as clear, preferred, first line treatment for epilepsy, it could not justify the excesses that were observed.[9] On this basis it concluded that the prices charged by Pfizer and Flynn were not only excessive but also unfair "in themselves", and hence that limb two of the United Brands test was met.

5. Under this scheme pharmaceutical companies are allowed to set prices of their branded portfolio of products in order to cover their direct and indirect costs (including an allocation of R&D costs) and to earn profits of up to 6%, measured as a return on sales and subject to a margin of tolerance.

6. The phenytoin sodium tablet and the phenytoin sodium capsule constitute near-identical products in their clinical usage. However, for the reasons discussed below, they are not clinical substitutes for stabilised patients.

7. As Pfizer's upstream supply price was set by reference to the downstream price charged by Flynn to the NHS this also resulted in an increase in the price charged by Pfizer as the upstream supplier of the product. This resulted in the CMA opening investigations into Pfizer (in relation to its upstream supply price) and Flynn (in relation to the downstream price charged to the NHS).

8. It was an issue of some dispute whether the return on sales benchmark of 6% indeed represents a profit cap under the PPRS scheme.

9. First-line therapy is the first line of treatment applied following diagnosis. If this is not effective or tolerable, subsequent treatments will be applied. Phenytoin sodium represents a third-line therapy for the treatment of epilepsy.

The limits of cost-based benchmarks

The CMA's cost plus benchmark represented the foundation of its case against both Pfizer and Flynn. As such, a considerable amount of time was dedicated during the trial to the question of whether this represented a sensible conceptual benchmark against which to assess prices.

The CMA's expert sought to justify the use of the "cost plus 6%" benchmark by arguing that this was a sensible measure of the price that a firm could charge to just cover the (long-run) costs incurred in producing a product or service and provide a return to investors to facilitate their ongoing participation in the market. RBB argued that this is the minimum price that a firm could sustainably charge and should not be confused with the range of prices that might be charged by companies in markets characterised by normal and sufficiently effective competition, reflecting factors such as the desirability of their products. RBB further noted that firms (including pharmaceutical companies) will often, under conditions of effective competition, set prices significantly above this level, reflecting their advantages as a supplier.[10] As such, RBB submitted that the CMA's "cost plus 6%" benchmark sets an unrealistically low benchmark for the determination of excessive pricing.

On this issue, the CAT was unequivocal in its support for the view that the conceptual approach employed by the CMA and its expert was flawed. It concluded that the CMA should have set a benchmark that reflected the spread of prices set (and margins earned) under normal competitive conditions.[11]

This in turn represents a significant victory for common sense over the form based approach applied by the CMA and sets a far higher threshold for establishing a robust finding of excessive pricing: namely, that prices must not only exceed costs but that they must be excessive when viewed in the wider industry context.

Measuring economic value

The CMA's approach to measuring economic value was another major battleground during the trial. The CMA acknowledged in this regard that Pfizer's phenytoin sodium offered patients whose medical conditions were stabilised using this product benefits that others could not. Indeed, it went as far as to say those patients were "totally dependent" on this product.[12]

However, rather than seek to incorporate into its price benchmark an allowance for the unique benefits the product offered to patients, the CMA took the stark view that, over and above the cost plus 6% benchmark, zero value should be ascribed to a product to reflect its unique benefits to patients in these circumstances. To do otherwise, it argued, would allow firms selling essential products to earn unreasonably high margins reflecting the dependency of consumers. Rather, the CMA took the view that by virtue of phenytoin sodium being old and not standing out as clear, preferred, first line treatment, no uplift was warranted.

By contrast RBB submitted, and the CAT agreed, that a more nuanced approach was necessary. In particular, whilst the CAT recognised that a dominant supplier should not be free to set any price that it likes with impunity from the law, just because (some) consumers view it as essential such that they value it highly, it considered that some allowance must be made for the "significant contribution" of phenytoin to treating epilepsy for a significant number of patients.[13] Put simply, if it is reasonable for a company to charge a price above cost for a product that people desire and value then it is also reasonable for a dominant company to charge some uplift for products that are so important to consumers that they require them.

In this regard, the CAT Judgment presents a second, significant, hurdle to establishing a robust finding of excessive pricing: namely a sensible benchmark for the value of products must be identified, reflecting the unique benefits they offer to consumers.

10. For example, pharmaceutical companies will often charge comparatively high prices for branded products even when they face generic competition to reflect the value of their brand.

11. CAT Judgment paragraph 321 and 324. Notably, the CAT is not prescriptive in how this test should be applied but does note that the CMA could have considered various candidate comparator products and companies more carefully.

12. In this regard the CMA pointed to guidance from the Medicines and Healthcare products and Regulatory Agency ('MHRA') which stated that individuals should not be switched to other versions of this product (including generic alternatives).

13. CAT Judgment paragraph 417.

Benchmarking against comparator products

Benchmarking against a range of comparator products offers one pragmatic approach to understanding whether the price of a specific product has been set at an excessive level. In particular, where consumers reveal themselves as willing to pay a similar or higher price for a product (or products) that is (or are) characteristically similar to the product under investigation in a market where there exists effective competition then that would tend to indicate that the prices under investigation are unlikely to be excessive. For this reason, Pfizer and Flynn placed significant emphasis on benchmarks – and in particular the phenytoin sodium tablet price (which exceeded the price of the capsule) – in their submissions.[14]

By contrast the CMA placed very little emphasis on benchmarks. It argued in the first instance that it was not legally required to do so and that (even if it was) no good benchmarks existed.[15] The CMA also went on to reject the tablet benchmark primarily on the basis that its price had also increased over time, and that it was subject to similar MHRA guidance on switching that limited competition in the capsule segment. Overall, it argued that this price was neither "cost-justified" nor able to act as a benchmark for competitive prices.

Again, the CAT was critical of the CMA's response to these submissions and its decision to dismiss (with little analysis) any and all benchmarks submitted by Pfizer and Flynn. With regard to the tablet the CAT noted that the CMA had concluded, without fully investigating, that the tablet market was not competitive, noting that the CMA had not explored basic information on market shares, competitor numbers and pricing and discounting which pointed to that market being subject to competition.[16] Given this fundamental oversight in the CMA's analysis, the CAT has, subject to appeal, in essence sent the CMA back to the drawing board to reassess fully competitive conditions in the tablet market and to determine if it did indeed represent a sensible benchmark for competitive prices. More generally, as noted above, the Judgment indicates that the CMA ought to have considered the wider industry context by reflecting a broad range of comparators when assessing these issues.[17]

Conclusion

The CAT Judgment rightly criticises the CMA's attempts to avoid many of the key issues inherent in assessing whether prices are excessive including how to consider the economic value of products that are important to consumers; how to evaluate the appropriate benchmarks; and ultimately how to sensibly take into account the fact that, in many markets, simply looking at costs does not provide a sensible guide to pricing that might be observed under normal competitive conditions.

In doing so, it also appropriately sets a high bar for a claim of excessive pricing to be robustly established under competition law: an authority should not only consider the wider context of the pricing and profits within the industry but must also objectively judge the value of products sold by (allegedly) dominant firms which by their nature have some benefits that cannot be offered by other alternatives. If upheld, the Judgment therefore reduces the risk of further misdiagnoses of excessive pricing in the future.

14. Pfizer and Flynn viewed that tablet as a clear benchmark because it is a product that does not compete with the phenytoin sodium capsule but is in other ways almost identical to it.

15. Specifically, the CMA submitted that the second limb of the United Brands test is alternative and not cumulative, such that, having established that prices are unfair in themselves, it did not need to consider whether or not they were unfair relative to comparators.

16. CAT Judgment paragraphs 380 and footnote 75.

17. CAT Judgment paragraph 324. This approach is consistent with that espoused in Advocate General Wahl's Opinion in a recent case concerning a claim of excessive pricing by the Latvian collecting society, available here: http://curia.europa.eu/juris/document/document.jsf?text=&docid=189662&pageIndex=0&doclang=EN&mode=lst&dir=&occ=first&part=1&cid=1273145%5d.